DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 20, 2015

iCare Newlife Technologies, Inc.
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Consulting Co., Ltd
7th Floor, Jingui Business Building, No. 982 Congyun Rd.
Baiyun District, Guangdong 510240
China

Re: K142769
Trade/Device Name: Fetal Doppler
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: HEK
Dated: February 17, 2015
Received: February 18, 2015

Dear Mike Gu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142769

Device Name
Fetal Doppler

Indications for Use *(Describe)*

The iCareNewlife Fetal Doppler is indicated for monitoring fetal heart rate during the antepartum period as a general indication of fetal well-being. The device is for hearing fetal heart sounds through the speaker only. The device is intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Diagnostic Ultrasound Indications for Use

Fetal Doppler (K142769)

Intended Use: Detect fetal heart rate as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal				N			
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

iCare Newlife Technologies, Inc.

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Secondary Contact Person: Mr. Bo Xiao

Vice President

iCare Newlife Technologies, Inc.

Date Prepared: 17 March, 2015

II. DEVICE

Name of Device:	iCareNewlife Fetal Doppler
Common/Usual Name:	Fetal Monitor
Classification Names:	Fetal ultrasonic monitor and accessories (21 CFR 884.2660)
Regulation Class:	II
Product Code:	HEK

III. PREDICATE DEVICE

Fetal Doppler JPD-100S, K110124.

This predicate has not been subject to a design-related recall.

IV. INDICATION FOR USE

The iCareNewlife Fetal Doppler is indicated for monitoring fetal heart rate during the antepartum period as a general indication of fetal well-being. The device is for hearing fetal heart sounds through the speaker only. The device is intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The Indications for Use statement for the iCareNewlife Fetal Doppler is not identical to the predicate device; however, the differences do not alter the intended diagnostic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the detecting of fetal heart beat.

V. DEVICE DESCRIPTION

The device is a hand-held ultrasonic fetal heart beat detector, which can detect the Fetal Heart Rate (FHR). The built-in speaker of the device allows for listening of the fetal heartbeat. The device is generally applied to above 16 weeks gestation.

Ultrasonic wave is transmitted from one piezoelectric ceramic at the front of the probe to the uterus of the pregnant women. Echo is received by the other piezoelectric ceramic at the front of the probe when ultrasonic wave reaches the fetal heart. Then it is converted into voltage. This Doppler signal is detected and demodulated from the received signal. And the Doppler frequency is consistent with the rhythm of the fetal systole and diastole. Once cardiac valves vibrate and a Doppler frequency excursion is formed. It is transmitted an output signal of cardiac valves vibrating, and it is sent to the loudspeaker for getting a rhythmical sound with the fetal heartbeat.

The device is powered by a 9V alkaline battery.

VI. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench testing

The device was evaluated for levels of acoustic output.

Biocompatibility testing:

The biocompatibility evaluation for the iCare Newlife Fetal Doppler was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological

Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the iCare Newlife Fetal Doppler. The device complies with the IEC 60601-1, IEC 60601-2-37 standards for safety and the IEC 60601-1-2 standard for EMC.

VII. Predicate Device Comparison

Descriptor	**Subject device**	**Fetal Doppler JPD-100S (K110124)**
Intended use	detect FHR	detect FHR
Sensitivity	16 weeks gestation	12 weeks gestation
Mode of operation	Continuous wave	Continuous wave
Ultrasound frequency	2.5 MHz	3.0 MHz
Ultrasonic power	≤22 mW	13.3 mW
Area corresponding to entrance beam dimensions	1.57 cm^2	2.65 cm^2
Acoustic output	14.01 mW/cm^2 (actual max value measured)	5.02 mW/cm^2
FHR measuring range	50~210 bpm	50~210 bpm
FHR resolution	1 bpm	1 bpm
Accuracy	± 2 bpm	± 2 bpm
FHR readout	Speaker sound	Speaker sound
Power supply	9V alkaline battery	9V alkaline battery
Transducer housing material	ABS plastic	ABS plastic

Substantial Equivalence Discussion

- Intended use – The subject and predicate devices have the same intended use – to detect the FHR. The predicate device can detect the FHR from 12 weeks gestation whereas the subject device can detect the FHR from 16 weeks gestation. The difference does not raise any effectiveness concerns, because the subject device is labeled for detecting the FHR during the antepartum period.

- Technological characteristics – Similarity in design

  The subject and predicate devices have the same fundamental design. They have the following same or comparable technological characteristics:

  * Mode of operation
  * Ultrasound frequency
  * FHR measuring range
  * FHR resolution
  * Accuracy
  * FHR readout
  * Power supply

- Technological characteristics – Difference in design

  The subject device has higher ultrasonic power and smaller area corresponding to entrance beam dimensions, resulting in higher acoustic output. The differences do not raise safety concerns, because the statistical maximum acoustic output of the subject device meets the requirement (≤20 mW/cm^2 for unfocused CW FHR devices) in the FDA guidance document, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" (issued on September 09, 2008).

- Material – The subject and predicate device use the same type of material – ABS plastic. To ensure safety, the subject device has been evaluated for biocompatibility, and the results demonstrated the subject device is safe.

In conclusion, the subject device is substantial equivalent to the predicate device in terms of safety and effectiveness.